# FINAL STATEMENT OF REASONS
# TITLE 27, CALIFORNIA CODE OF REGULATIONS

## SECTION 25305, SCIENCE ADVISORY BOARD, POWERS AND DUTIES
## SECTION 25701, NO SIGNIFICANT RISK LEVELS, GENERAL
## SECTION 25705, NO SIGNIFICANT RISK LEVELS, SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK
## SECTION 25801, NO OBSERVABLE EFFECT LEVELS, GENERAL

UPDATE OF INITIAL STATEMENT OF REASONS

The amendments as originally noticed to the public, will modify sections 25305, 25701, 25705, and 25801 as follows:

Section **25305** sets out the powers and duties of the Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicant Identification Committee (DARTIC). The amendment would add Subsections 25305(a)(6) and 25305(b)(6) to the existing regulation to clarify that the CIC and DARTIC are provided with the scientific basis for No Significant Risk Levels (NSRLs) and Maximum Allowable Dose Levels (MADLs), respectively.

Section **25701** contains the general regulations for the NRSLs. Section 25705(b)(2) currently provides that the notice of rulemaking and the Initial Statement of Reasons for that regulatory action be provided to each member of the CIC during the public comment period prior to the lead agency's adoption of an NSRL pursuant to Subsection 25705(b)(1). The amendment revises and moves this provision from Subsection 25705(b)(2) to Subsection 25701(e) to clarify that rulemakings initiated under *all* provisions of Article 7 are to be sent to the CIC for scientific peer review.

Section **25801** currently does not expressly require the lead agency to send the notice of proposed action and Initial Statement of Reasons for proposed MADLs or other regulations to the DARTIC. The regulatory amendment adds Subsection 25801(f) to clarify that rulemakings initiated under Article 8 are to be sent to the DARTIC for scientific peer review.

## SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE COMMENT PERIOD OF MARCH 23, 2012 THROUGH MAY 7, 2012.

One comment was received from Ms. Joyce Dillard. This comment stated the following:

"The addition of Section 25305 Powers and Duties has no allowance if no scientific information exists or if an incomplete study exists. This appears to automatically void any action by the reviewing committees.
There also appears to be no allowance for creation of State Clearinghouse or other method of accumulating scientific information. It cannot be assumed that the Lead Agency will go into a significant level of researching for a study.
The proposed regulation does not require more than one study, if more than one exists.
The proposed regulation does not require the disclosure of funding for the study.
Is it the intent to let a party responsible for the chemical or exposure to a chemical also fund a study that may reduce effects or clear risks of an adverse health effect and in essence, eliminate any legal liability."

These comments are not responsive to the amendments. The changes only clarify the Office of Environmental Health Hazard Assessment's (OEHHA) existing practice of submitting proposed Maximum Allowable Dose Levels and No Significant Risk Levels for peer review by members of the Carcinogen Identification Committee and Developmental and Reproductive Toxicant Identification Committees. The comment addresses other subsections in section 25305 that are not being modified in these regulatory amendments. However, the comment will be taken into consideration by OEHHA in any future proposed amendments to section 25305.

**ALTERNATIVES DETERMINATION**

One alternative to the committee members conducting peer reviews would be to establish a contract for scientific peer reviews with the University of California or a similar institution of higher learning, but this would increase the cost and time taken for the reviews significantly, and would be inefficient. The committee members are the state's designated experts on carcinogens and reproductive toxicants, and as such are an exceptional resource for peer review of documents on these subjects. The committee members have experience reviewing such documents and can provide a more experienced and expedited review, which is helpful to businesses and individuals who need these NSRLs and MADLs to determine if they must provide a warning for exposures to listed chemicals or if they are prohibited from discharging a listed chemical into a source of drinking water.

Therefore, in accordance with Government Code, section 11346.9(a)(4), OEHHA

has determined that no reasonable alternative considered by OEHHA or that has otherwise been identified and brought to the attention of OEHHA would either be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this Notice.

## LOCAL MANDATE DETERMINATION

OEHHA has determined this regulatory action will not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action. It should be noted that all state and local government agencies are expressly exempt from Proposition 65. Thus, these regulatory amendments will not impose any mandate on local agencies or school districts.